

REMARKS

This submission is in response to the Official Action dated March 8, 2002. Claim 4 has been amended. Claims 4, 8 and 9 are pending. New claim 9 has been added. Reconsideration of the above identified application, in view of the above amendments and the following remarks, is respectfully requested.

Claim 4 has been amended to recite the culturing of *Phellinus linteus* Yoo deposited in the Korean Collection for Type Cultures (Deposition No. KCTC 0399BP) at a constant temperature of 28°C for about 5 days, isolating the substance by precipitating in ethanol at 4°C for about 24, and dialyzing with a dialysis tube at 10°C for about 72 hours. Support for the amendments of claim 4 can be found on, *e.g.*, page 6, lines 20-21; page 26 Example VIII, and page 27 Example IX.

New claim 9 is fully supported by the specification as filed, specifically at page 27, Example X.

No new matter has been added by way of this amendment.

Statement Under 37 C.F.R. 1.808

Applicants hereby certify that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in this patent application.

Non-Obviousness

The Examiner holds claims 4 and 8 as being obvious over the teachings of Lee et al.(hereinafter "Lee"), in view of U.S. Patent No. 4,051,314 to Ohtsuka (hereinafter "Ohtsuka"); U.S. Patent No. 4,877, 777 to DiLuzio (hereinafter "DiLuzio") and KR 97-15743[N] to Cho et al (hereinafter "Cho.").

Applicants respectfully disagree. The references cited by the Examiner do not teach or suggest the method and polysaccharide composition of the invention, as set forth by the amended claims.

To establish a *prima facie* case for obviousness under 35 U.S.C. § 103(a), three basic criteria must be met. First, there must be some suggestion or motivation to modify what is taught in a reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference or combination of references must teach all of the claim limitations. Both the motivation and the reasonable expectation of success must be found in the prior art, not in applicant's disclosure. See, M.P.E.P. § 2143, citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

As explained below, the cited patents do not render the claims obvious under these and other requirements.

The Lee reference describes a method of producing polysaccharides from fungal cultures including cultures belonging to *Phellinus sp.* However, this reference does not teach or suggest an incubation of 28°C for about 5 days as defined in the

present claims. In addition, Lee does not describe or suggest dialyzing for about 72 hours or purifying the substance, in sequence with gel filtration or otherwise, DEAE-cellulose chromatography.

The Ohtsuka reference relates to the preparation of cultures, including cultures belonging to the *Phellinus* family, by hot water extraction, ethanol precipitation, water suspension, dialysis, and purification procedures such as cellulose chromatography, gel-chromatography, and ion exchange chromatography, and the Cho reference relates to the purification of *Phellinus linteus* polysaccharides by using DEAE-cellulose chromatography. However, neither one of these references teaches the production of polysaccharides by incubation at 28°C for about 5 days.¹

Finally, the DiLuzio reference describes fungal polysaccharide substances which are comprised of glucose units joined by $\alpha(1\rightarrow4)$ and $\beta(1\rightarrow6)$ linkages. However, this reference does not describe *Phellinus sp* polysaccharides or incubation of such cultures at 28°C for 5 days.

Accordingly, it is respectfully submitted that there would have been no motivation to combine the DiLuzio reference with the Lee, Ohtsuka or Cho references. The DiLuzio reference does not relate to the optimization or even production of *Phellinus sp* polysaccharides. Therefore, there would have been no motivation to combine this reference with Lee, Ohtsuka, and/or Cho, in order to obtain the method of claim 4 or the polysaccharide of claim 8. Accordingly, the amended claims are not

¹ The term "28°C" does not occur in the Cho reference.

obvious over the references cited by the Examiner.

In addition, even if the references were to be combined, they do not teach or suggest the present claim limitations. For example, all of the cited references are silent with respect to the incubation of *Phellinus sp.* at 28°C for about 5 days as called for in claim 4. The Examiner is respectfully directed to Example VIII (p. 26) and Figure 2 of the instant specification. As described in this Example, it was surprisingly noted that the *Phellinus sp.* culture reaches its essential maximum production yield after about 5 days (see Fig. 2) as opposed to the 10 days of culturing at 30°C disclosed in Lee (see Lee, col. 2, page 326) and the 23-25°C incubation for 20 days disclosed in Ohtsuka (see Ohtsuka, col. 7, line 7). Thus, amended claim 4 sets forth an optimized method for efficient production of polysaccharides from *Phellinus sp.* in a shorter period of time. Moreover, the method of new claim 9 includes, by reference, these optimized conditions for polysaccharide production.

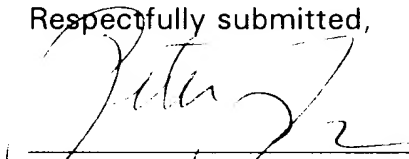
It is the present applicants and not the prior art that disclose the methods defined by the present claims. It is only by using the applicants invention (as set forth in this application) as part of the prior art that the examiner is able to synthesize reasons for rejecting the present claims under the guise of obviousness. The courts have condemned the practice of hindsight reconstruction. (cite case) Accordingly, the present claims are believed to be patentable over the art of record and such action is earnestly solicited.

In summary, it is respectfully submitted that the Examiner's rejection as

applied to the amended claims fails to meet the requirements for *prima facie* obviousness. Thus, reconsideration and withdrawal of this rejection is respectfully requested.

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,



S. Peter Ludwig
Reg. No. 25,351
Attorney for Applicants

DARBY & DARBY, P.C.
Post Office Box 5257
New York, NY 10150-5257
Phone (212) 527-7700



RECEIVED
AUG 21 2002

TECH CENTER 1600/290

EXPRESS MAIL CERTIFICATE

Date 8/9/02 Label No. EU186683749-45

I hereby certify that, on the date indicated above, this paper or fee was deposited with the U.S. Postal Service & that it was addressed for delivery to the Assistant Commissioner for Patents, Washington, DC 20231 by "Express Mail Post Office to Addressee" service

PLEASE CHARGE ANY DEFICIENCY UP TO \$300.00 OR CREDIT ANY EXCESS IN THE FEES DUE WITH THIS DOCUMENT TO OUR DEPOSIT ACCOUNT NO. 04-0100

Name (Print) B.W. LEE Signature B.W. Lee

Customer No.:



Docket No: 1728/1F088

07278

PATENT TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Ick-Dong Yoo et al.

Serial No.: 09/846,634

Art Unit: 1651

Confirmation No.: 5673

Filed: MAY 1, 2001

Examiner: Vera Afremova

For: NOVEL IMMUNO-STIMULATING POLYSACCHARIDE SUBSTANCE FROM PHELLINUS SPP. STRAIN AND USE THEREOF

MARK-UP FOR RESPONSE TO OFFICE ACTION

Hon. Commissioner of
Patents and Trademarks
Washington, DC 20231

August 8, 2002

Sir:

IN THE CLAIMS:

4. (Twice Amended) A method for preparing a novel immuno-stimulating polysaccharide substance, comprising the steps of

culturing *Phellinus linteus* Yoo [(KCTC 0399BP)] deposited under the accession number KCTC 0399BP on media containing glucose, yeast extract and peptone to give mycelia or fruiting bodies at 28°C for about 5 days ;

extracting the substance from the mycelia or fruiting bodies by hot water;

isolating the substance by precipitating in ethanol at 4°C for about 24 hours, suspending in water and dialyzing with a dialysis tube at 10°C for about 72 hours;

purifying the substance by sequentially executing DEAE-cellulose chromatography and gel chromatography.